



I-Corps from the Trenches

Conversations with I-Corps Alum

October 26, 2017

Christie Canaria Program Director

National Cancer Institute SBIR Development Center





Q&A

sbir.cancer.gov/icorps
Submit your questions through the Q&A chat box

Please submit your questions via the chat box. We will be answering your questions throughout the webinar, with additional time dedicated at the end of the session.







Christie Canaria NCI/NIH I-Corps

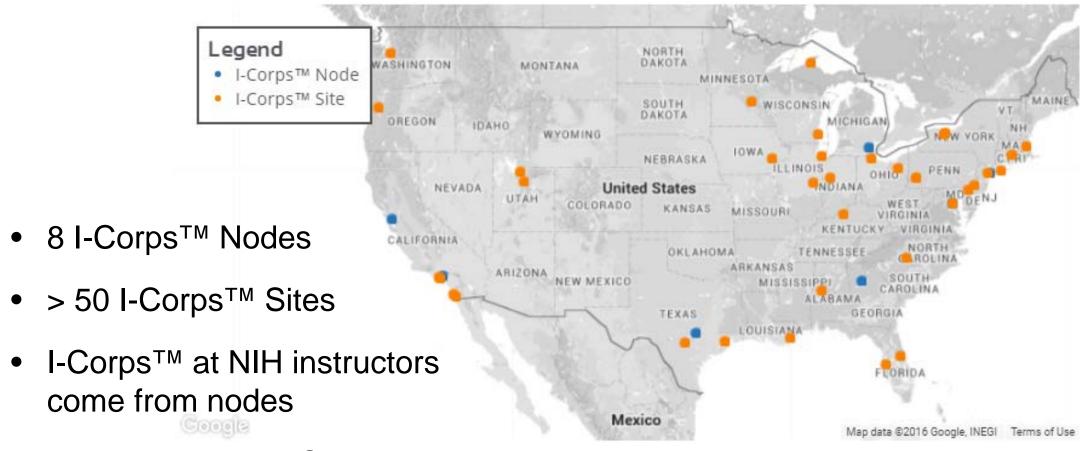


Edmund Pendleton Lead Instructor



Michael Schultz CSO, Viewpoint Molecular Targeting

NSF National Innovation Network



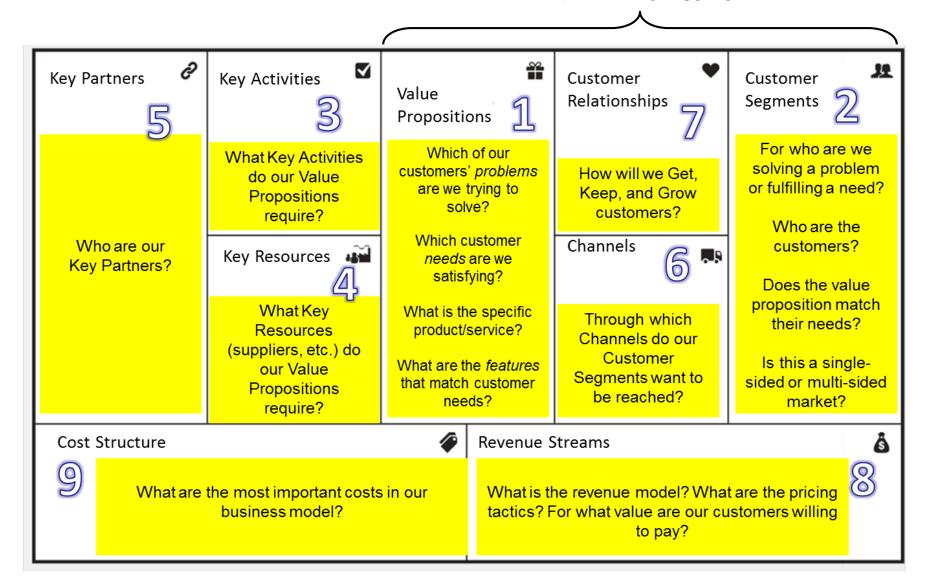
 Trained with I-Corps curriculum

I-Corps™ Training Program Program Description

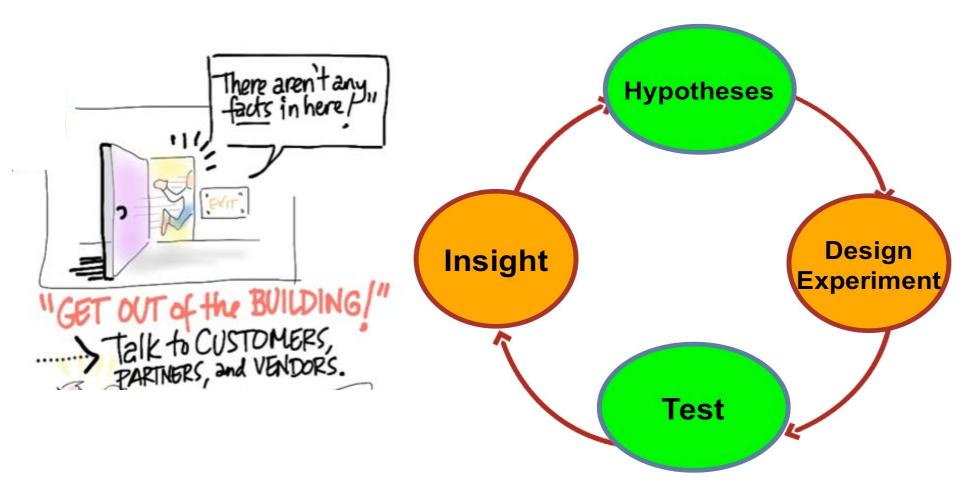
- •Intensive *Entrepreneurial Immersion* course aimed at providing teams with skills and strategies to reduce commercialization risk
- •Curriculum emphasizes *Reaching out to Customers* to test hypotheses about the need and market for the technology being developed.
- Each team is expected to conduct over 100 interviews over 8 weeks.
- Format is focused on Experiential Learning

Business Model Canvas

" Product-Market Fit "



Hypotheses Testing and Insight...



Focus on Learning

Customer development is **NOT** sales!

- Teams are not pitching their product or technology
- Teams are listening to potential customers and other stakeholders and learning about:
 - What customers want and need
 - Pain points in their customers' daily routines
 - Features of a technology that would provide value

I-Corps™ at NIH - Program Format

THERAPEUTICS TRACK

THERAPEUTICS Expert

DIAGNOSTIC TOOLS TRACK

DIAGNOSTICS & eHEALTH Expert

I-Corps Node Instructor

I-Corps Node Instructor

MEDICAL DEVICES
TRACK

MED DEVICE Expert

I-Corps Node Instructor

COURSE FORMAT

- 3-Day Kick-off Event
- 6 Weekly web classes
- 2-Day Lessons Learned

TEAM STRUCTURE

- C-level executive (decision making authority)
- PD/PI (strong technical background)
- Industry Expert
 (rolodex & experience)

LIFE SCIENCE TRACKS

- Therapeutics
- Diagnostics/eHealth
- Medical Devices
- Teams are distributed among track "rooms"

TEACHING TEAM

- I-Corps Node Instructors
- Industry Domain Experts
- Curriculum tailored to life sciences



I-Corps[™] at NIH



5 cohorts to date

- •100 teams conducted 10,000+ customer discovery interviews
- •90% found the program "very good" or "excellent"
- •90% would recommend I-Corps™ at NIH to other companies

"We clarified the value propositions, who our target customers would be, revenue streams, customer relationships..."

"After going through I-Corps we understand we have to focus on a small subset [of customers] and prioritize segments based on their value propositions."

I-Corps[™] at NIH

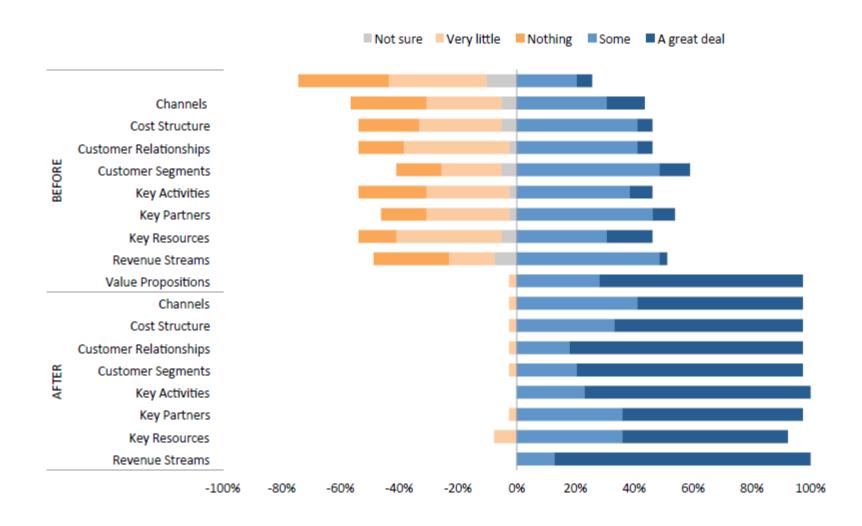
SBIR/STTR Phase II grant applications have two components

- 1. The Research Strategy
- 2. The Commercialization Plan
- Phase II applicants often focus on #1
- The strongest Phase II applications focus on both

Important goal of I-Corps™ at NIH is to inform the Commercialization Plan

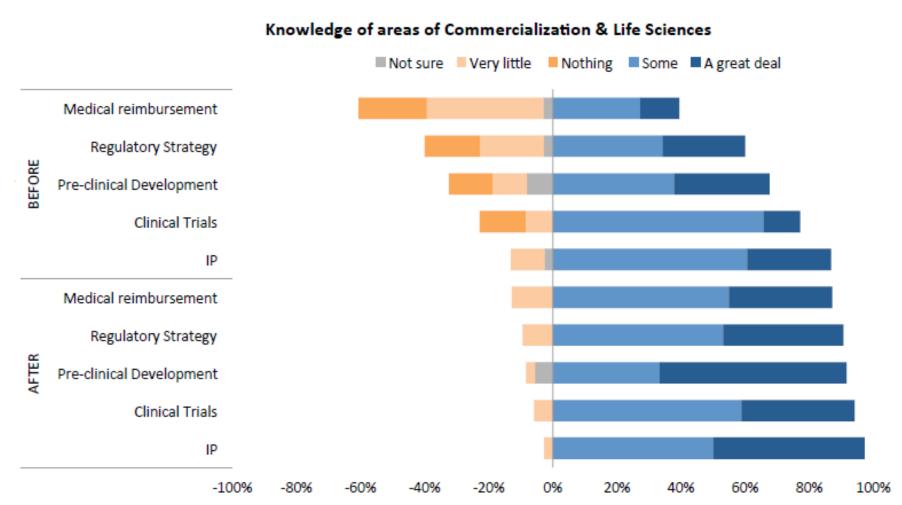
Business Model Canvas Knowledge

Spring 2016 Cohort



Life Science Commercialization Knowledge

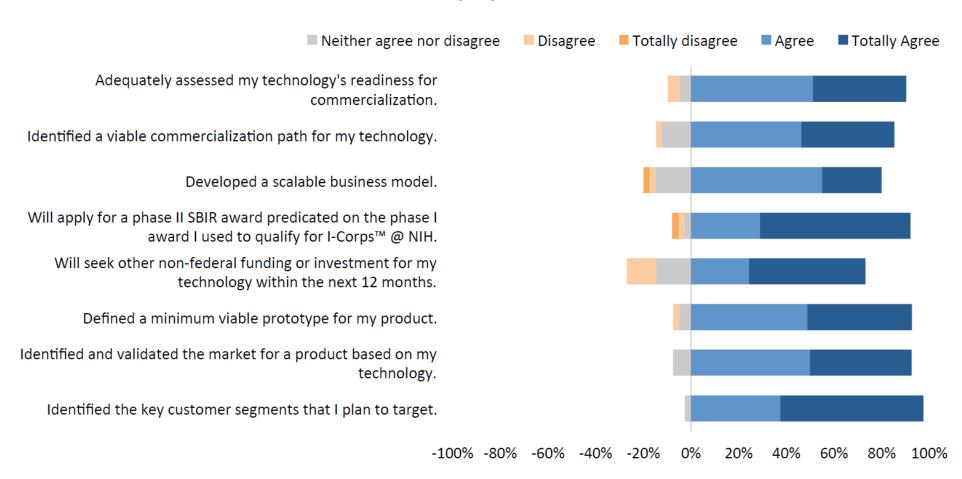
Spring 2016 Cohort



Status of Technology and Future Plans

Spring 2016 Cohort

Company Status





16 Participating ICs in 2018

- National Cancer Institute (NCI)
- National Human Genome Research Institute (NHGRI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute of Allergy and Infectious
 Diseases (NIAID)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute of Dental and Craniofacial Research (NIDCR)

- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Emerging Zoonotic and Infectious Diseases (NCEZID/CDC)
- National Institute for Occupational Safety and Health (NIOSH/CDC)

Apply to I-Corps using ASSIST

with these instructions may be delayed or not accepted for review.

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system to system to system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.

Apply Online Using ASSIST

Apply Using Downloadable Forms

Problems accossing or using ASSIST should be directed to the eRA Service Desk.

Problems downloading forms should be directed to Grants.gov Customer Support.

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Part 2 Full Text of Announcement

Section I. Funding Opportunity Description

Background

America's prosperity has originated in part from the ability to capitalize economically on ground-breaking discoveries from science and engineering research. Simultaneously, a knowledgeable, creative U.S. workforce has maintained the country's global leadership in critical areas of technology. These important discoveries and capable workforce resulted from substantial, sustained investment in science and engineering. A strong capacity for leveraging fundamental scientific discoveries into powerful engines of innovation is essential to maintain our competitive edge in the future.



I-Corps[™] at NIH



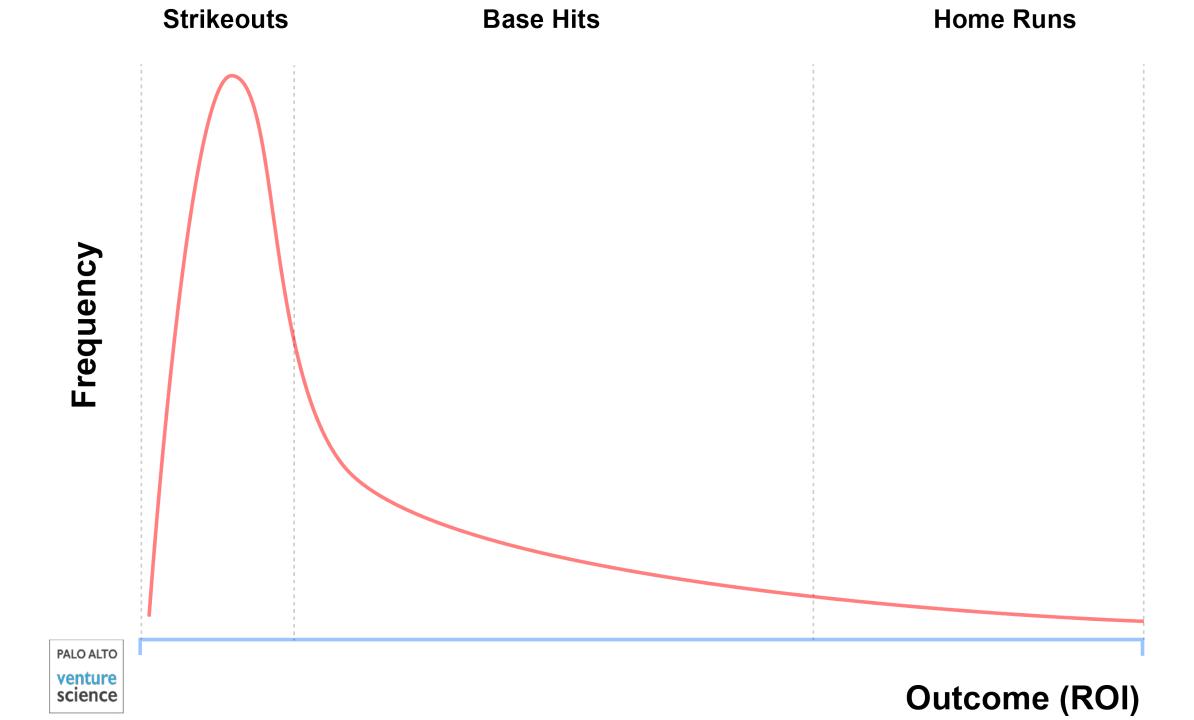
PA-18-314 I-Corps at NIH Administrative Supplement \$50,000 budget cap

	·
Application Due Date	December 18, 2017
Phone Interview (estimated)	January 29, 2018
Notice of Award (estimated)	February 2018
Kick-off/Close-out Venue	TBD
Course Kick-off	April 9-12, 2018 (Monday-Thursday)
Web-Ex Courses	Wednesdays
(1-5PM ET)	Apr 18
	Apr 25
	May 2
	May 9
	May 16
	May 23
Course Close-out/	May 31 – Jun 1, 2018
Lessons Learned	
Cohort Size	24 teams

https://grants.nih.gov/grants/guide/pa-files/PA-18-314.html

Next Application Deadline: December 18, 2017

Why I-Corps



More startups fail from a

lack of customers

than from product failure

More startups fail from a

lack of customers

than from product failure

----- STARTUP MISTAKES **Hiring Poorly** Score: 153 18% of Tot. **Building something Lack of Focus** nobody wants Score: 112 Score: 300 13% of Tot. 36% of Tot. Score: 98 12% of Tot. Fail to execute Sales & Marketing 100 First#Hits# www.100FirstHits.com **5.** Not Having The Right **66** (7,9%) 8. Spending Too Much Money 18 (2,1%) Co-Founders 9. Failing To Ask 12 (1,4%) 6. Chasing Investors, **45** (5,4%) For Help Not Customers **10.** Ignoring Social **6** (0.7%) 7. Not Making Sure You Have Enough Money Media



Hiring Poorly

Score: 153

18% of Tot.

Lack of Focus

Score: 112

13% of Tot.

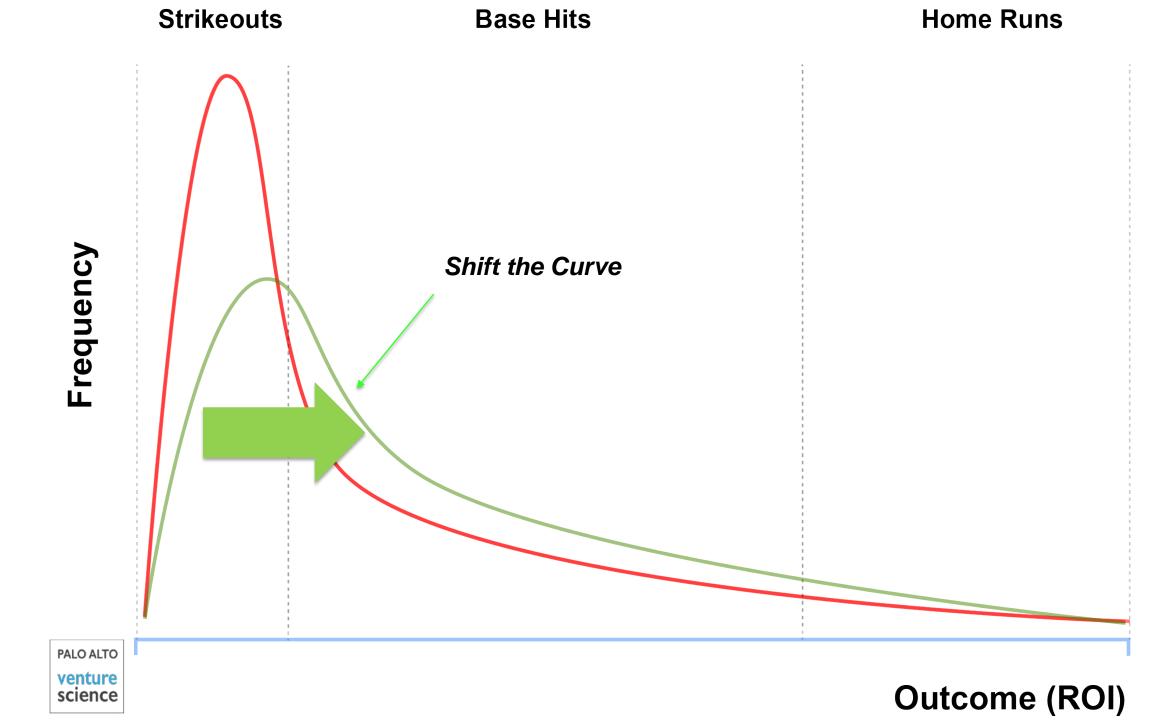
Score: 300

Building something

nobody wants

Our Goal

Improve Odds



ALSO

Innovation Culture Change

Invention Innovation

Invention about Technology

Innovation about Customer Needs

Solutions Based to Needs Based

Get out of the building!

TEST and VALIDATE assumptions

It's not only about helping patients...

...or making the science work...

Your goal is to build a business.

What to expect from instructors?

Teaching Team



Practitioners... not Academics

Coaches... not Consultants

How to think... not what to think.

Respectfully Direct

What make a good team?



Viewpoint's ICORPS Story

Academic Entrepreneurship and True Grit

Michael K Schultz PhD Chief Science Officer



Heyward Coleman MBA, CEO











Industry Expert



Principal Investigator

Product: Targeted radiotherapy for metastatic melanoma.

Business Thesis: Initially, medical oncologists caring for metastatic melanoma patients who have failed current therapies will prescribe our product because it will improve survival by 6 months in greater than 20% of patients, with the potential to expand to front line therapy for all metastatic melanoma patients.

	Interview Count			C
TOTAL	105	77	2	26

Medical Oncologists (16)
Radiation Oncologists (5)
Nuclear Medicine/Radiologist Physicians (21)
Physician Assistants/Nurses (4)
Radio/Nuclear Pharmacist/Chemists (18)
Industry Experts/CRO (24)
Legal (3)
Regulatory (2)

Financial (12)



Viewpoint Management Team



Heyward Coleman MS, MBA – Co-Founder, CEO

- 40+ years' experience as business executive and entrepreneur
- Founder of largest private radiochemistry company in U.S.
 (Environmental Physics, Inc. acquired by General Engineering Laboratories, LLC)
- Corporate spin-off experience at Maritrans GP, Inc.
- MS Nuclear Physics at Duke and MBA at Harvard



Michael Schultz PhD - Co-Founder, CSO

- 15+ years' industry and research experience in radioactivity/nuclear medicine
- Associate Professor of Radiology and Nuclear Medicine at the University of Iowa
- Expert in targeted radiotherapies for cancer
- Business manager experience with Ametek Inc. (ORTEC brand)



Frances Johnson MD – Co-Founder, CMO

- 22 years' experience as Clinical Trials PI
- Co-founded molecular diagnostic company (XDx, Inc. now CareDx, Inc.)
- Adjunct Associate Professor at University of Iowa
- MD University of Washington, Residency UC San Francisco, Faculty Stanford, University of Maryland, and University of Iowa

We didn't know, what we didn't know



- 2011 \$25,000 Elevator pitch (University of Iowa)
- 2013 \$150,000 Phase I SBIR
- 2015 \$150,000 Phase I SBIR \$300,000 Phase I SBIR (contract) \$25,000 Iowa Innovation Corporation \$100,000 State of Iowa Demo Funds
- 2016 \$300,000 Phase I SBIR
- \$100,000 Wellmark Funds
- 2017 \$50,000 NCI ICORPS Program
 \$2,000,000 Phase II SBIR (contract)

Goals



- What is ICORPS?
- Who are we?
- Where are we?
- Is ICORPS right for us?
- Are we right for ICORPS?



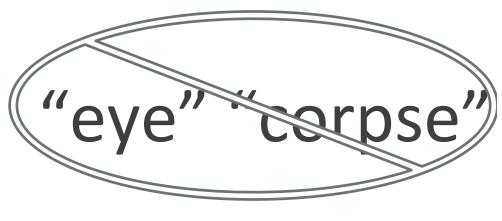
ICORPS

"eye" "core"

An intensive entrepreneurship program that emphasizes customer discovery as the means to energize your business.



ICORPS







Who are we? Why are we here?





- Great idea
- Start up company
- Next level
- ICORPS might help

"academic entrepreneur"



Academic Entrepreneurship?

ac-a-dem-ic; akə'demik/ adjective

- 1. relating to **education** and **scholarship**.
- 2. not of practical relevance; of only theoretical interest.

noun

a teacher or scholar in a college or institute of higher education.

Academic Entrepreneurship?

en·tre·pre·neur·ship ¡äntrəprəˈnərˌSHip/ noun



the activity of setting up a business or businesses, taking on <u>financial risks</u> in the hope of **profit**.

Technology Continuum & ROI



Purely Academic SBIR Phase I



Purely Commercial



Academic Discovery Grants/Papers R01/R21



Technology Transfer SBIR Phase II Equity



EDGE
The R-Rated Superstar
"ROI"

Why do most startups fail?



	The founders fight
	They can't build their initial spec
	No one will fund their idea
	Too few people will buy/use the product



Why do most startups fail?



The founders fight

They can't build their initial spec

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Who are we? Where are we?





TRUE GRIT



Are we right for ICORPS?



TRUE GRIT

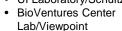
- C-suite executives
- Time to participate
- Wants to contribute big
- Knowledge and skills
- Excited about it



We didn't know what we didn't know...

Business Model Canvas-1

Key Partners Key Activities National Institutes of Health · Safety and efficacy in UI Research Foundation animals and human trials **UI Ventures** · Regulatory approvals and **Economic Development** compliance Corporation · Development of Iowa Economic manufacturing and Development Authority distribution processes Private Equity Investors Develop customer support and technical personnel Department of Energy · Assure supply of Lantheus Medical Imaging radioisotopes Supply Chain Manufacturers Key Resources Eckert Ziegler Eurotope National Cancer Institute UI Laboratory/Schultz Midwest Melanoma



- - Patent Rights
 - Clinical Expertise

 - · Business Expertise

0

- SBIR Funding
- UIRF

- Technical Expertise

Value Propositions



and save lives

- Viewpoint's radiopharmaceutical is a good prospect for acquisition for several specialized pharma
- Our product uses a companion imaging scan to select patients that can benefit from our therapy and predict response.
- Melanoma develops resistance to all current approved drugs on the market today. Our product can be used as an adjuvant with any of

Customer Relationships Big Pharma

pecialized Pharma-Cancer nerapy & Imaging

Contract Research **Organizations**

Patient Advocacy Groups

Physicians and **Patients**

Channels

Melanoma Clinics

A.

- Healthcare Organizations
- Patient Advocacy Groups
- Sales and Distribution
- Clinical Site Support

Customer Segments



- Metastatic melanoma patients
- Physicians caring for metastatic melanoma patients
- Nuclear Medicine physicians and staff
- Healthcare organizations that care for metastatic melanoma patients
- Pharma companies expaning presence in melanoma market
- CMS and Reimbursement
- FDA Regulatory

Cost Structure

Partnership

University of Iowa

Mayo Clinic, Rochester

- · Safety and efficacy in animals and human trials
- · Regulatory approvals and compliance
- Development of manufacturing and

- Manufacturing and distribution
- Customer support and technical personnel
- Radioisotopes

approved herapy. Revenue Streams

· Build value toward acquisition.





We didn't know what we didn't know...

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Business Model Canvas-1

Key Partners National Ins



- UI Research Foundation
- UI Ventures
- Economic Develo
- lowa Econor
 Developm
 thority
- Private F nvestors
- Depart of Energy
- Lanth Medical Imaging
- Sup hain Ma turers
- Ec
 Ziegler Eurotope
- Name I Cancer Institute
- Melanoma
 Paship
- Ur ity of lowa
- Malinic, Rochester

ues

Safety and efficacy in animals and human trials Regulatory approvals and

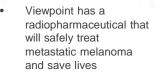
- ment of
 man ing and
 distributes sesses
- Develop cu support and technical support
- Assure supply of radioisotopes

Kev Resources

key Resources

- UI Laboratory/Schultz
- BioVentures Center Lab/Viewpoint
- SBIR Funding
- UIRF
- Patent Rights
- Clinical Expertise
- Technical Expertise
- Business Expertise

Value Propositions



- Viewpoint's radiopharmaceutical is a good prospect for acquisition for several specialized pharma
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Customer Re Big Pharma

Specialized Pharma-Cancer
Therapy & Imaging

Contract Research Organizations

Patient Advocacy Groups

Physicians and Patients

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Customer Segments

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Cost Structure

- Safety and each in animals and humans
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- Manufacturing and distribution
- Customer support and technical personnel
- Radioisotopes

approved therapy.

Revenue Streams

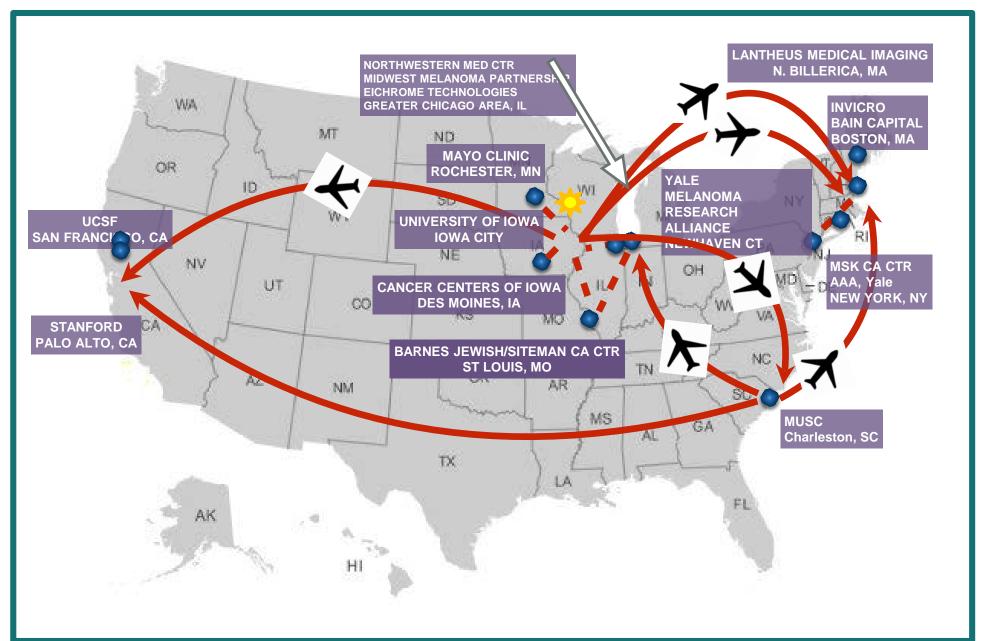
Build value toward acquisition.

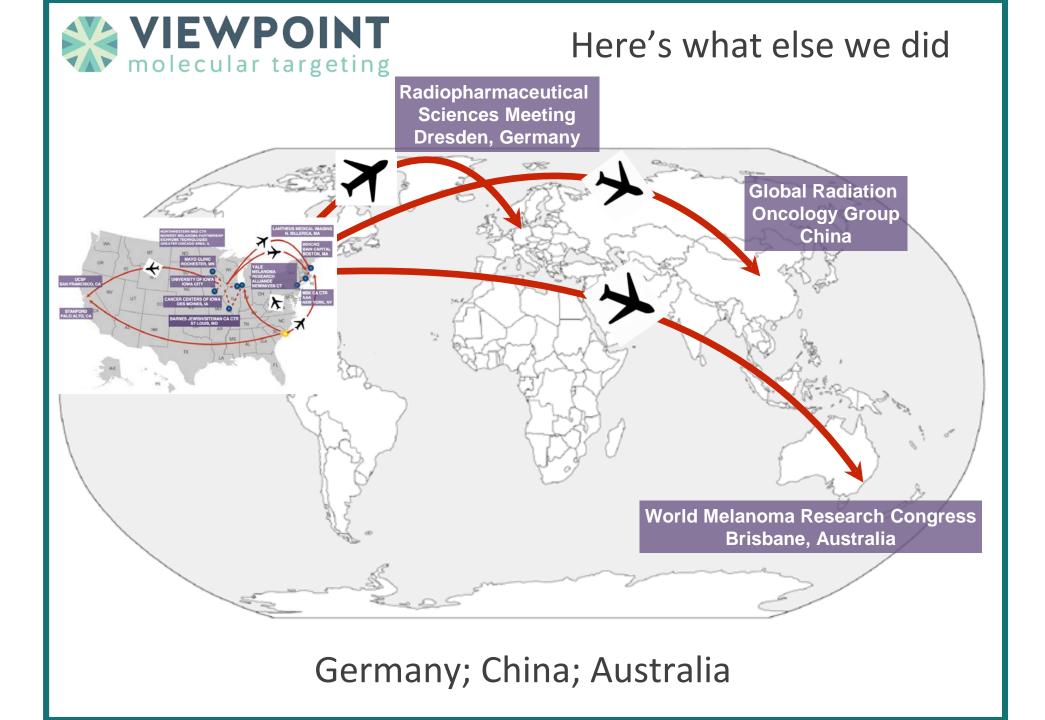






So, here's what we did







And, here's who we talked to







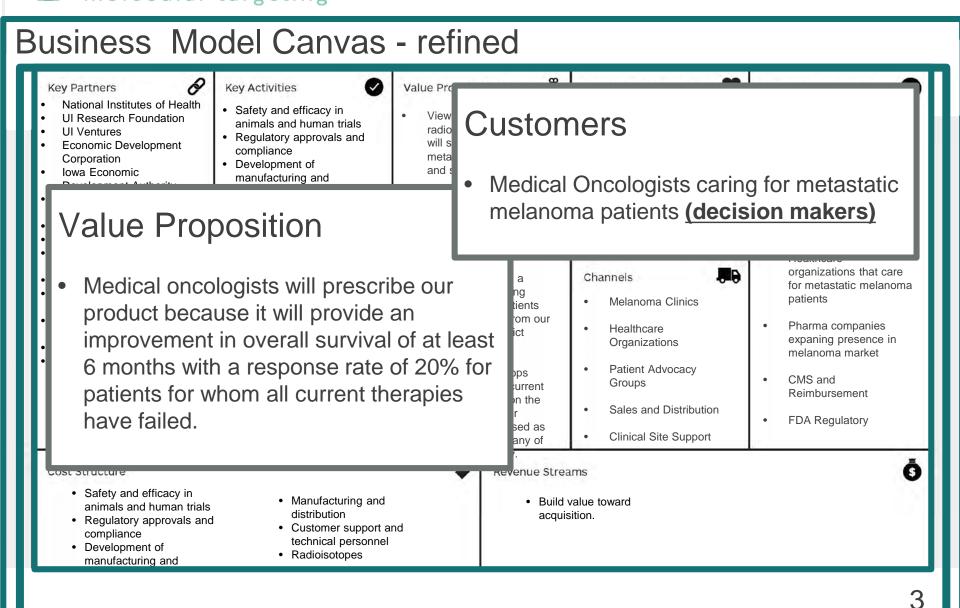
Medical oncologists would prescribe our therapy with an expectation of $\underline{6}$ months increased survival and a 20% response rate (n = 16; **34**).

Dr. Mohammed Milhem (Founder Midwest Melanoma Partnership) "6 mo improved survival in 20% of patients is exciting..."





Refined understanding



Letting go... the diagnostic myth

We thought we had two products; a therapeutic and a companion diagnostic, but <u>finally</u> after n = 40.



"Don't do the diagnostic. It is going to hurt your therapeutic at best!"

George Segall MD; Director of Nuclear Medicine, Stanford University Palo Alto Veterans Administration Hospitlcal

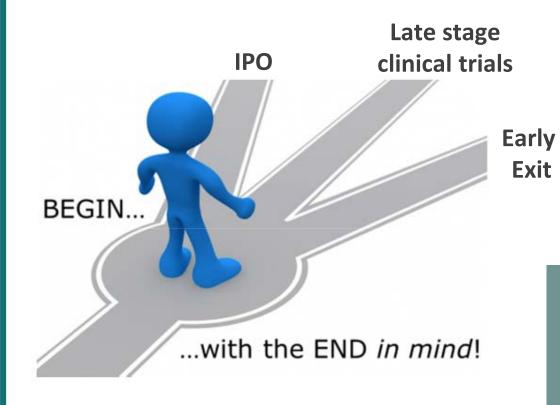


We learned we have one!

Is ICORPS right for us?



The end of the beginning...



- TEAM CHEMISTRY
- OPEN MIND
- TIME TO DEVOTE
- START RIGHT NOW



"Business is NOT the easy part!"
Nancy Kamei PhD

ICORPS is right for us.



- START PLANNING INTERVIEWS NOW
- REVIEW YOUR PLAN/RESULTS EVERY WEEK
- CLEAR YOUR CALENDAR NOW
- BE PREPARED TO BE INTERRUPTED
- Interviews are not selling your product
- Interviews are not pitching your company
- Interviews are open ended conversations about your market space

THANK YOU!







I-Corps™ at NIH



Q&A

sbir.cancer.gov/icorps
Submit your questions through the Q&A chat box